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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/564,443

01/12/2006

Stewart Anderson

4662-128

7492

23117

7590

09/25/2008

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EXAMINER

HOLT, ANDRIAE M

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

09/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,443	Applicant(s) ANDERSON ET AL.	
	Examiner Andriae M. Holt	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/12/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending in the application. Claims 1-16 will be examined on the merits.

Priority

Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.

This application is a 371 of PCT/EP04/09781 filed September 2, 2004, which claims priority to European Patent Office Application 03019881.6 filed September 2, 2003.

Information Disclosure Statement

The examiner acknowledges receipt of the Information Disclosure Statement dated January 1, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "adsorbant" in line 2 of the claim. There is insufficient antecedent basis for this limitation in the claim. The claim references the “

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amount of adsorbant in claim 9". Claim 9 does not contain an adsorbant as one of the components of the granulate composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-8 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyota et al. (WO 03/086099)

Miyota et al. disclose a stabilized vitamin C exhibiting high vitamin C titer which is reduced only to a minimum extent during the course of production and storage (page 3, paragraph 1). Miyota et al. disclose a fish-farming solid feed containing a stabilized vitamin C that contains at least one kind of oil selected from vegetable oil and animal oil (page 4, claims 1-5). Miyota et al. disclose the stabilized vitamin C is a salt of L-ascorbate 2-phosphate (ascorbyl (poly) phosphate, instant invention). Miyota et al. further disclose the preferred vitamin C is selected from at least one salt consisting of magnesium, calcium, sodium, and potassium salts of L-ascorbate 2-phosphate (page 4, claim 10), including a sodium/calcium mixed salt of L-ascorbate 2 phosphate (page 7, paragraph 1). Miyota et al. disclose that it is preferable in view of stability that stabilized vitamin C is applied as an oily slurry which is a dispersion in at least one oil selected from vegetable oils and animal oils. Miyota et al. further disclose that when an oil slurry

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is used, stabilize vitamin C has reduced chance of contacting with water and its decomposition due to hydrolysis can be minimized (page 8, paragraph 4-page 9, paragraph 1).

Miyota et al. disclose the average particle size of a stabilized vitamin C particle is in the range of 5 μ m to 300 μ m (page 6, paragraph 17). Miyota et al. further disclose stabilized vitamin C is retained at a high ratio in the fish-farming solid feed, at least 60% by mass (page 12, paragraph 3) (5% to about 40% ascorbic acid equivalent, instant invention). Miyota et al. disclose the fish-farming solid feed contains at least 10% by weight more preferably 10% to 40% by weight of the vegetable and/or animal oil (page 11, paragraph 2) (amount of lipid, 10%-60%, instant invention). Miyota et al. disclose in magnesium salt of L-ascorbate 2-phosphate was dispersed in fish oil to prepare an oily APM suspension. Miyota et al. further disclose the feed pellets were immersed in the oily APM suspension (page 16, paragraph 1) (adsorbent, instant invention).

Miyota et al. meet all of the limitations of the claims and the claims are thereby anticipated.

Claims 1-3, 6, 8-10, 12, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogata et al. (JP06181695).

Ogata et al. disclose that there when using L-ascorbic acid 2-phosphoric ester there is high L-ascorbic acid activity in almost all living things including metal and bacteria of certain kind, such as the enzyme and acid that exists in biogenic substances, such as a germ of the wheat which may be added by feed, and fish meal in

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wheat bran and a feed raw material and iron. Ogata et al. further disclose that this promotes disassembly of ascorbic acid-2-phosphoric acid and that the concentration of L-ascorbic acid 2-phosphoric acid falls (page 2, paragraph 9).

Ogata et al. disclose to a method that enables one to keep stable L-ascorbic acid-2-phosphoric acid in feed, thus decreasing the disassembly of ascorbic acid 2-phosphoric acid (page 2, paragraph 10). Ogata et al. disclose the L-ascorbic acid 2-phosphoric acid is dissolved in hardening plant and animal oil fat with a melting point of not less than 40° C (method of stabilizing ascorbyl (poly) phosphate against degradation by phosphatases, instant invention) (page 2, Means of Solving the Problem).

Ogata et al. disclose in example 4, L-ascorbic acid 2-sodium phosphate (sodium calcium ascorbyl 2-polyphosphate, instant invention), dibasic calcium phosphate, calcium carbonate, calcium lactate, potassium metaphosphate, and beef tallow extreme hydrogenated oil (lipid, instant invention) were fed into the agitation granulation machine. Ogata et al. further disclose the melting heating granulation was performed and the granule of 20-42 meshes was obtained (page 4, paragraph 25). Applicant uses the term "comprising" in the claims, therefore, lending to the inclusion of other products.

Ogata et al. disclose examples of salts of L-ascorbic acid 2-phosphoric acid include L-ascorbic acid 2 monophosphate (trisodium ascorbyl 2-monophosphate, instant invention) and L-ascorbic acid-2-polyphosphoric acid including salts of sodium and calcium (page 2, paragraph 11). Ogata et al. disclose examples of the oil include palm oil and hardening oleum rapae (page 3, paragraph 12). Ogata et al. further

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disclose the amount of oil and fat used is 10% by weight or more of the composition (amount of lipid 10 wt %, instant invention). Ogata et al. disclose in the description of the prior art that L-ascorbic acid is added to feed for land animals such as swine and cows (animal feed for ruminants, instant invention).

Ogata et al. meet all of the limitations of the claims and the claims are thereby anticipated.

Claims 9-10 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Alexis Publication (1999).

The Alexis Publication discloses a comparative study of stabilized phosphate esters of ascorbic acid, including mono (AmP) and polyphosphates (ApP) (Introduction). The Alexis Publication teaches that phosphate esters of ascorbic acid (AA), in the form of mono-(AmP) and polyphosphates (ApP) have been found to be more stable than the acid form. The Alexis Publication discloses the common practical formula was prepared as described in Table 1 (page 448, 2.1). The Alexis Publication discloses the premix used contained all essential vitamins and minerals except for the ascorbic acid. The Alexis Publication discloses diet 2 included ascorbyl-2-monophosphate; diet 3 included ROVIMIX Stay C 25 (mainly polyphosphate); and diet 4 included ROVIMIX Stay C35 (mainly monophosphate). The Alexis Publication discloses all the dry components of the diet were mixed in a Hobart mixer and water and oil were added to obtain a soft paste (trisodium L-ascorbyl-2-monophosphate and sodium calcium L-ascorbyl-2-polyphosphate and oil, instant invention). The Alexis Publication discloses the paste

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was passed through a mincer and dried at 35° C in a forced air circulator. The Alexis Publication discloses that pellets were crumbled to an appropriate size, screened and fed to the fish (animal feed and premixes, instant invention).

The Alexis Publication meets all of the limitations of the claims and the claims are thereby anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Kubota et al. (US 5,229,147) in view of The Alexis Publication (1999).

Applicant's Invention

Applicant claims granulate compositions and a method of stabilizing ascorbyl (poly) phosphate against degradation by phosphatases by coating the ascorbyl (poly) phosphate with a lipid. Applicant further claims the granulate composition comprises trisodium L-ascorbyl-2-monophosphate or sodium calcium L-ascorbyl-2-polyphosphate.

***Determination of the scope of the content of the prior art
(MPEP 2141.01)***

Kubota et al. teach a coated vitamin C preparation for animal feed comprising a particulate core containing vitamin C and a coating material composed of one or more fine powdery lipids having a melting point of at least 40° C (Abstract). Kubota et al. teach that concrete examples of particulate vitamin C include L-ascorbic acid, DL-ascorbic acid and 6-desoxyascorbic acid; salts of these acids with metal cations such as calcium, and sodium (col. 3, lines 6-11). Kubota et al. further teach these products can be employed solely or in combination of two or more of them for the core substance of the coated preparation (col. 3, lines 14-16). Kubota et al. teach fatty substances that may be employed include various lipids, such as natural fats and oils, hardened oils, and waxes (lipids, oils and waxes, instant invention) (col. 3, lines 22-25). Kubota et al. teach the starting weight of the particulate is at least 50%. Kubota et al. further teach the particle size is in the range of 0.1 to 1,000 µm which is 0.0001 mm to 1 mm (col. 3,

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lines 29-34) (particle size, 0.1 to 1.0 mm, instant invention). Kubota et al. teach the coated vitamin C preparation is useful for supplementing animal feeds by admixing it with conventional feed components such as to be received by livestock, poultry and marine culture animals(col. 5, lines 42-46) (animal feed, instant invention). Kubota et al. teach the coated Vitamin C effectively isolates vitamin C core particles from external influences of other components, radiant rays, heat, moisture and ambient atmosphere. Kubota et al. teach the preparation provides preservation of the physiological activity of vitamin C for longer periods of time. Kubota et al. teach the absorbability of vitamin C of the preparation by animals is quite high, thus, an efficient absorption of vitamin C by organisms can be attained (col. 5, lines 53-66).

Kubota et al. teach in example 1 the preparation of the composition. Kubota et al. teach that 150 g of the hardened rapeseed oil coating material was added to 350 g of a particulate product of L-ascorbic acid. The 150 g of rapeseed oil makes up 28% of the composition (10 wt % to 60 wt% of lipid, instant invention).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Kubota et al. do not teach the use of ascorbyl (poly) phosphate or specifically teach stabilizing against degradation by phosphatases. It is for this reason the Alexis Publication is joined.

The teachings of the Alexis Publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed above.

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Kubota et al. and the Alexis Publication and use ascorbyl (poly) phosphate as the ascorbic acid component (vitamin C). The Alexis Publication teaches that phosphate esters of ascorbic acid in the form of mono- and polyphosphates are more stable than the acid form itself and highly available. The Publication also teaches that oil is added to the composition. Thus, one skilled in the art at the time the invention was made would have been motivated to use an ascorbyl (poly) phosphate in the composition to produce a more stable vitamin C additive because ascorbyl (poly) phosphate is a more stable vitamin C component to start with.

Each of the references is silent to the protection of ascorbyl (poly) phosphate against degradation by phosphatases, however, the compositions of the prior art, particularly, the Alexis Publication, are the same as Applicant's composition, an ascorbyl (poly) phosphate coated with a lipid. Thus, the skilled artisan would recognize that a composition is inseparable from its properties. Hence, all the properties associated with Applicant's compositions would also be possessed by the compositions of the prior art. In addition, Kubota et al. teach that by coating vitamin C components, the components or core particles are protected from external influences of other components, radiant rays, heat, moisture and ambient temperatures and the coating

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provides effective preservation of the physiological activity of vitamin C for longer periods of time.

Given the state of the art as evidenced by the teachings of the cited references, and absent any evidence to the contrary, there would have been a reasonable expectation of success in combining the teachings of the cited references to produce a stable ascorbyl (poly) phosphate that is protected from external influences of other components, radiant rays, heat, moisture, ambient temperatures and provides effectively preservation of the physiological activity of vitamin C for longer periods of time.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

None of the claims are allowed

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
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/John Pak/
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